

RESPONSE

In the specification, paragraphs [0030] and [0031] have been amended to correct minor typographical errors. The errors and the corrections would be obvious to the skilled artisan based on the context.

Claims 1-94 were pending in the subject application. Claims 1-94 stand subject to restriction and election requirements. Claims 37 and 38 are amended. Claims 95-98 are added. Accordingly, claims 1-98 are pending in the subject application.

Claims 37 and 38 are amended to correct minor typographical errors. New claims 95-98 are added to more clearly define the subject matter of the present invention. Support for the amendments may be found in the originally filed specification, more specifically, for example, at paragraphs [0041] and [0373] of the originally filed specification. No new matter was added. None of the amendments or new claims is being introduced for reasons relating to patentability.

Election / Restriction

As noted by the Examiner, Applicants have elected, with traverse, the invention of Group 4, which is drawn to compounds wherein V is -CH₂-, -CH=CH-, or -C≡C-, and A¹-A⁴ do not contain a ring. Further, as also noted by the Examiner, Applicants have elected, with traverse, the species of Example 44.3, trans-methyl-{4-[5-(methyl-propyl-amino)-pent-1-ynyl]-cyclohexyl}-carbamic acid 4-chloro-phenyl ester.

Applicants note that at least claims 1, 37 and 93 are claims linking arguably distinct inventions. Therefore, pursuant to MPEP § 809, the linking claims must be examined with the invention elected, and should any linking claim be allowed, the restriction requirement must be withdrawn. Any claims directed to the nonelected inventions, previously withdrawn from consideration, which depends from or includes all the limitations of the allowable linking claim must be rejoined and must be fully examined for patentability. Therefore, should the invention of Group 4 be found allowable, Applicants submit that the MPEP requires full patentability examination of previously withdrawn claims directed to the nonelected inventions.

Also as noted above, Applicants have elected the species of Example 44.3; and this species falls within the invention of Group 4. At least claims 1-4, 8-11, 13, 15-17, 21-22, 24-30, 36-38, 40, 45, 84-85 and 95-98 are readable, at least in part, upon this species. Applicants submit that pursuant to 37 CFR § 1.141, upon allowance of a generic claim, Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim.

Further, Applicants note that election of species should not be required if the species claimed are considered clearly unpatentable (obvious) over each other. See MPEP § 808.01(a). Therefore, should the Examiner hold any election requirement as being final, Applicants request that the Examiner note, in the record, that each of the remaining species, not rejoined into the allowable generic claim, are patentably distinct from each of the species examined.

Section 112 Enablement Rejections

The Examiner rejected claims 1-94 under 35 U.S.C. 112, first paragraph, assertedly “because the specification does not provide enablement for A6 equal to all heteroaryl, heteroaryl-lower-alkyl, or A1 [and] A3 bonding together to form all of the heterocyclic rings as claimed.” Applicants respectfully disagree and submit that the specification fully teaches the invention as claimed, and does enable the making and using of all embodiments across the full scope of the claims.

The Examiner posits that the above-described embodiments cannot be made, based on the disclosure in the specification, without undue experimentation. However, the fact that some experimentation or even a considerable amount of experimentation is necessary does not necessarily lead to the conclusion that enablement is lacking; the invention is deemed enabled so long as the amount of experimentation required is “not ... unduly extensive.” Atlas Powder Co. v. E.I. DuPont de Nemours & Co., 750 F.2d 1569, 1576 (Fed. Cir. 1984). Notably, the Board of Patent Appeals and Interferences explained:

The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Jackson, 217 U.S.P.Q. 807, 807 (B.P.A.I. 1982).

In this case, the specification provides ample guidance to enable the skilled artisan to practice the embodiments in question. Specifically, the specification teaches several general methods to introduce A⁶ groups, including heteroaryl and heteroaryl-lower-alkyl groups. For example, scheme 3, which is depicted on page 56 of the specification) and described in detail in

paragraphs [0066] through [0078], demonstrates how various A⁶ groups may be introduced. In addition, numerous examples are provided of compounds that include heteroaryl or heteroaryl-lower-alkyl A⁶ groups, including, for example, Examples 5.5, 5.7, 5.12, 5.38, 6.1, 6.2, 6.8 and 6.10.

The specification, at paragraph [0054], further teaches that:

The compounds of formula (I) can be manufactured by the methods given below, by the methods given in the examples or by analogous methods. Appropriate reaction conditions for the individual reaction steps are known to the person skilled in the art. Starting materials are either commercially available or can be prepared by methods analogous to the methods given in the examples or by methods known in the art.

Hence, having been provided with such detailed instructions, a person skilled in the art would readily be able to synthesize compounds having various heteroaryl and heteroaryl-lower-alkyl A⁶ groups by substituting various starting materials and by making appropriate changes to the specific methods taught in the specification.

Likewise, the specification provides ample guidance with respect to synthesizing compounds wherein A¹ and A³ are bonded together to form a heterocyclic ring. For example, in scheme 5 (depicted on page 58 and described in detail in paragraphs [0083] through [0091]) demonstrates how to introduce various A¹ – A⁴ groups, including those wherein A¹ and A³ are bonded together to form a heterocyclic ring. A skilled artisan would recognize that, by using a building block **10** having a heterocyclic ring formed by A¹ and A³, one could synthesize a compound of formula (I) wherein A¹ and A³ form a heterocyclic ring.

The specification further teaches that such building blocks **10** can be prepared by known methods. Indeed, many of these building block compounds having a heterocyclic ring are commercially available. For example, the compound, 2-(2-chloroethyl)-1-methylpyrrolidine hydrochloride, may be ordered from the Sigma Aldrich catalog (Product No. 13,952-1).

Serial No. 09/925,188
Filed: August 9, 2001

Finally, Applicants submit that the Wands factors, when properly analyzed, weigh heavily in favor of a finding that the claims are fully enabled. Applicants note that the specification provides ample and detailed direction as to how to practice the claimed embodiments (Wands factor #6), and provides literally hundreds of working examples (Wands factor #7). Furthermore, Applicants assert that the quantity of experimentation (Wands factor #8) needed to practice the invention (in light of the aforementioned guidance/direction provided by the specification) is very reasonable and certainly not "unduly extensive." See In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

Applicants suggest that an interview with the Examiner would assist in furthering prosecution of the subject application. Accordingly, Applicants respectfully request an interview with the Examiner, to be scheduled at the Examiner's convenience.

No fee, other than the fee for the additional claims and the fee for a two-month extension of time, is required in connection with the filing of this communication. If any additional fee is deemed necessary, authorization is given to charge the amount of any such fee to deposit account no. 08-2525.

Respectfully submitted,

Peter Tu

Attorney for Applicant(s)

Peter Tu

(Reg. No. 43,207)

340 Kingsland Street

Nutley, New Jersey 07110

Telephone: (973) 235-2884

Telefax: (973) 235-2363

136500